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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	50150/064001	4322

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --.

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *6-29 and 40-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 49-51* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed October 2, 2006 is acknowledged. Claims 30-39 are canceled. In the last Office Action an election of Group II, claims 1-5, 30-39 and 49-51, was made without traverse. Claims 6-29 and 40-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 1-5 and 49-51 remain under consideration.

A new title is noted and the Abstract of the disclosure has been amended. Accordingly, the objections to the disclosure are withdrawn.

In the last Office Action claims 1-5,30-39 and 49-51 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of various co-pending applications. The conflicting claims are not identical, but they are not patentably distinct from each other because the claims of the co-pending applications recite pharmaceutical compositions or formulations comprising rifalazil.

Applicants choose to hold these issues in abeyance. The provisional obviousness-type double patenting rejections of record of claims 1-5 and 49-51 are maintained over claims 43-45 of copending Application No. 10/948608; over claim 4 of copending Application No. 11/020870; and over claim 4 of copending Application No. 11/008597.

Claims 30-39 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention.

These rejections of record under 35 U.S.C. 112 are moot following the cancellation of the claims.

Claims 1-5, 30-39 and 49-51 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sayada, C.B., US 2003/0236265.

This rejection under 35 U.S.C. 103 is withdrawn because the inventors of US 2003/0236265 had a common obligation to assign their rights to ActivBiotics Incorporated at the time both of these inventions were made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Rose et al., U.S. Patent 6,316,433.

Rose teaches pharmaceutical compositions comprising a unit dosage form of rifalazil in an amount at least of 1 mg or 5 mg for oral administration. See column 11, lines 38-53, Drug Formulation, lines 64, column 32, to column 33, line 4, as well as claims 11 and 16 in column 34.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences.

Rose teaches pharmaceutical compositions comprising a unit dosage form of rifalazil in an amount at least of 1 mg or 5 mg for oral administration. See column 11, lines 38-53, Drug Formulation, lines 64, column 32, to column 33, line 4, as well as claims 11 and 16 in column 34. Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosage units with a higher amount of active antibiotic in the first dosage unit. Such a dosing regimen, as taught by Remington, reflects conventional practice in that the first dose is a loading dose that is followed by a second dose, considered to be a maintenance dose. A therapeutic drug concentration can be achieved quickly by means of a large initial dose. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional. It has been held that Applicant is not entitled to

patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336,70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Lithander et al., British Journal of Ophthalmology, is cited to show further the state of the art with respect to administration of a loading dose of an antibiotic, followed by a lower, "maintenance" dose. See page 3.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 14, 2006

Phyllis Spivack

PHYLLIS SPIVACK
1614 PRIMARY EXAMINER